

# Notice of Allowability

Application No.

09/711,724

Examiner

Zachary C. Howard

Applicant(s)

TABIN ET AL.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/16/2005.
2. ☒ The allowed claim(s) is/are 1,3,7,17,27,29,30,32,34-36,42-44,47-49,63,66-69,78,92 and 94-97.
3. ☒ The drawings filed on 11/13/2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 6/20/01
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

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ROBERT S. LANDSMAN, Ph.D.  
PRIMARY EXAMINER

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### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Melissa Rones on 4/4/2005.

The application has been amended as follows:

In claim 1, after the phrase "indicates a *hedgehog*-mimicking", delete the word "activity" and insert the word "bioactivity" therefor.

In claim 17, after the phrase "An assay for" delete the words "screening test compounds to identify agents" and insert the words "identifying compounds" therefor.

In claim 17, part (c), after the phrase "detecting activation of the hedgehog pathway in the cell" delete the words "by detecting a change in *GLI* expression in the cell," and insert the words "by detecting an increase in the expression of the *GLI* gene in the cell or a decrease in the expression of the *GLI3* gene in the cell," therefor.

In claim 17, after the phrase "wherein a change in the level of activation of the hedgehog pathway is indicative of", delete the words "an agent" and insert the words "a compound" therefor.

In claim 30, after the phrase "An assay for" delete the words "screening test compounds to identify agents" and insert the words "identifying compounds" therefor.

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In claim 30, part (c), after the phrase "detecting a change in the hedgehog pathway in the cell" delete the words "by detecting a change in *GLI* expression in the cell," and insert the words "by detecting an increase in the expression of the *GLI* gene in the cell or a decrease in the expression of the *GLI3* gene in the cell," therefor.

In claim 30, after the phrase "wherein a change in", insert the words "the level of activation of"

In claim 30, after the phrase "the absence of the test compound, is indicative of", delete the words "an agent" and insert the words "a compound" therefor.

Cancel claim 31.

In claim 63, after the phrase "A method for identifying *hedgehog*" insert the word "pathway"

In Claim 63, after the phrase "the presence of the *hedgehog* protein is indicative of agonist activity of the test agent" insert the words "to the hedgehog pathway."

In claim 78, after the phrase, "An assay for" delete the words "screening test compounds to identify agents" and insert the words "identifying compounds" therefor.

In claim 78, part (b), after the phrase "detecting activation of the hedgehog pathway in said cell" delete the words "by detecting a change in *GLI* expression in the cell," and insert the words "by detecting an increase in the expression of the *GLI* gene in the cell or a decrease in the expression of the *GLI3* gene in the cell," therefor.

In claim 78, part (d), after the phrase "detecting activation of the hedgehog pathway in said cell" delete the words "by detecting a change in *GLI* expression in the cell," and

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insert the words "by detecting an increase in the expression of the *GLI* gene in the cell or a decrease in the expression of the *GLI3* gene in the cell," therefor.

In claim 78, after the words "compound in comparison to the absence of said test compound is indicative of" delete the words "an agent" and insert the words "a compound" therefor.

In claim 78, after the phrase "that antagonizes a bioactivity of a *hedgehog*" delete the word "protein" and insert the word "pathway" therefor.

Cancel claim 79.

Cancel claim 80.

In claim 92, line 1, after the phrase "A method for identifying hedgehog" insert the word "pathway"

In Claim 92, after the phrase "antagonist activity of the test compound" insert the words "to the hedgehog pathway."

In the specification, first paragraph (twice amended, most recently 9/2/2003) replace the words "...continuation-in-part of 08/462,386, filed on June 5,1995, which..." with "...continuation-in-part of 08/462,386, filed on June 5,1995, now abandoned, which..."

In the specification, page 2, before the phrase "Figure 5A is a...." insert the phrase "Figures 5A and 5B -"

## **EXAMINER'S COMMENT**

### ***Specification***

A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because the original specification, filed 11/13/2000, has several unreadable words near the top of each page, as a result of having an insufficient margin at the top of each page to prevent holes from being punched through the text when the specification was received and placed in a case wrapper.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

### ***Information Disclosure Statement***

References AN, AX, BD, DH, and FZ listed on the IDS submitted 6/20/2001 were fully considered but the citation on the IDS listing for each of these references is either missing a publication date or has a typographical error in the publication date. To correct this, these references have been removed (lined through) from the IDS and correct citation provided by the Examiner on a PTO-892 form (Notice of References cited). No action is required by the Applicants with regard to the IDS.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER